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(54) Cartridge-needle unit having retractable needle

Aus Kartusche und Nadel bestehende Einheit mit rückziehbarer Nadel

Ensemble à aiguille rétractable

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(56) References cited:
WO-A-90/01962
DE-A- 3 842 317
US-A- 4 808 169
US-A- 4 909 794
US-A- 4 944 723

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Description

This invention relates to a cartridge-needle unit having a needle that can retract within the cartridge after use for safe disposal and to a safety syringe assembly comprising such cartridge-needle unit.

Disposable medicament-containing cartridge needle units for use in conjunction with reusable hypodermic syringe holders are well known in the art and in widespread commercial use. Such cartridges conventionally feature a cylindrical body closed at the proximal end with a flexible plunger slidable within the bore of the cartridge and closed at the distal necked-down end with a septum secured to the cartridge by a crimped-on aluminum collar. The necked-down distal end conventionally is fitted with a needle hub/needle/needle sheath assembly. Such cartridge-needle units are available from Sanofi Winthrop Pharmaceuticals under the Carpuject® trademark.

In use, the cartridge-needle unit must be activated, i.e. the proximal end of the needle cannula must penetrate the sealed septum such that communication is achieved between the fluid and the proximal end of the needle. Some cartridge-needle units are sold in an activated form. Others must be activated by the user. When user-activated cartridge-needle units are used in conjunction with conventional reusable syringe holders of the type described, e.g. in Hadtke, U.S. Patent 4,585,445 and in EP-A-0 485,028, this is accomplished when the health care worker advances the cartridge through the holder by rotating a clamping element.

Many holders, including the above-referenced reusable holders, enable the user to avoid handling the cartridge-needle unit when the needle unit is exposed. Nevertheless, health care workers are especially susceptible to accidental and potentially infectious, and indeed, on occasion, possibly fatal, needle strikes due to the careless handling and/or disposing of the cartridge-needle unit after use. The consequences to health care workers of strikes from needles contaminated with various infectious diseases such as hepatitis or AIDS can be particularly severe. The frequency of accidental needle strikes in the United States is surprisingly great, and has been estimated to be approximately one million strikes per year. Moreover, the cost to health care organizations for the testing of health care workers accidentally stricken by used needles is a significant burden on health care costs. This is illustrated in a recent report by Kirkland, Safer Syringes Boost Molder Opportunities, Plastics World, August 1993, pp.20-24, which states:

"The average cost associated with accidental needle-stick injury in the U.S. reportedly is $3 billion/year. For example, estimates for the average cost associated with testing alone is at least $1,200 per injury. This does not take into account the cost of treatment if disease develops (estimated at $15,700), litigation costs, increased insurance premium costs, replacement of the injured worker, OSHA fines and other costs."

Therefore, it would be desirable to further protect health care workers by providing systems which reduce the possibility of accidental needle strikes.

To this end, it has been suggested to provide syringes having a retractable needle. For example, Haber et al, U.S. Patent 4,909,794, describe a combination retractable needle cannula and cannula lock for a medication carpule, i.e. cartridge. The cannula lock includes a clamp having a pair of jaws which are normally separated from one another so that the needle can be releasably retained therebetween. In the preinjection state, the clamp is axially spaced from the cartridge, and the jaws of the clamp are rotated towards one another to retain the cannula in an axially extended position for administering an injection. Post-injection, the health care worker continues to apply pressure to the piston stem forcing the empty cartridge to move forward such that the needle embeds in the plunger. Further movement displaces the clamp, whereby the jaws of the clamp rotate away from one another to release the cannula. The cannula may then be retracted within and completely surrounded by the empty cartridge so that the cannula can be safely discarded.

However, the system proposed in U.S. Patent 4,909,794 has been found to be less than satisfactory from a commercial standpoint for a variety of reasons, resulting from both inherent design limitations and reliability concerns.

Firstly, because the needle is released from the jaws of the clamp by the health care worker continuing to apply an axially and distally directed force beyond the point at which all medication is delivered, there is an unacceptably high probability that the health care worker may prematurely release the needle while it is still embedded in the patient. One possible consequence of this may be that the health care worker must then remove a lone sharp needle from the patient.

Secondly, unlike most current commercial hypodermic syringe designs, this prior art system relies upon an interference fit between the jaws and the hub in order to wedge the needle in place. In fact, Haber et al suggest that the proximal surface of the cannula be textured to enhance the frictional retention of the needle. However, if the frictional force is not great enough, the needle may slip with respect to the jaw both upon injection and removal from the patient. If the fit is too tight and the frictional force is too high, the user may have to deliver an unreasonably high force to release the jaw from the hub. More generally, friction is an unreliable force to use for such a critical function, inasmuch as small variations in dimension, surface finish, cleanliness, or even temperature can alter the desired retention force. While some modifications can be made to improve the reliability of this device and its use of friction, ultimately, there are limitations.

Thirdly, after the jaw is released from the hub, the

needle is freed to be withdrawn into the cartridge by the plunger. However, any body fluid and/or medication that may remain on the tip of the needle after removal from the patient can be wiped on the jaw as the needle is retracted. This body fluid then remains in an unprotected area and presents some level of danger to the health care worker.

Haber, U.S. Patent 4,935,014, which is a continuation-in-part of the above-described Haber et al patent, describes another combination retractable needle cannula and cannula lock embodiment in which the jaws of the clamp in the pre-injection state are surrounded by and rotated towards one another by an expandable outer sleeve which retains the cannula in an axially extended position between the jaws for administering an injection. Post-injection, the clamp is displaced outwardly of the sleeve, whereby the jaws are free to release the cannula. It appears that the sleeve enables the syringe to be adapted for use with a cartridge having a head which is narrower in diameter than the cylindrical body. In any event, the syringe described by Haber in U.S. Patent 4,935,014 contains jaws and suffers from the same inherent design limitations and reliability concerns as described above.

It would be desirable to provide a cartridge-needle unit having a retractable needle which

(1) reduces the tendency for body fluids and/or medication to remain in an unprotected area upon retraction of the needle into the cartridge,
(2) does not rely upon an unpredictable frictional fit between the needle and hub and
(3) virtually eliminates the possibility that the needle can be released into the patient.

According to the present invention there is provided an improved cartridge-needle unit comprising

a cartridge comprising

a hollow body,
a septum at the distal end of the body,
means for retaining the septum, and
a plunger axially and reciprocally slidable through the interior of the body;

a needle capable of being retracted within the cartridge,
a hub comprising

a sleeve adapted to be snapped on the distal end of the cartridge;
means for retaining the needle within the hub during an injection; and
means for releasing the needle from the hub after the injection characterised in that said means for releasing the needle from the hub and said means for retaining the needle within the hub comprise an element of greater diameter than said needle and attached thereto, said element abutting against a hub post before and during injection, said hub post being capable of forcing the element through the septum after injection and of separating the element from the remaining needle retaining means with a continued application of an axially and distally directed force on the plunger, the needle thus embedding into the plunger.

It is an advantageous feature of this invention that a cartridge-needle unit having a retractable needle is provided that virtually eliminates the possibility that the needle can be released into the patient.

It is another advantageous feature of this invention that a cartridge-needle unit having a retractable needle is provided having substantially improved reliability, thus reducing the susceptibility of health care workers to accidental needle strikes.

Another advantageous feature of this invention is that a retractable needle cartridge-needle unit is provided that reduces the tendency for body fluids and/or medication to remain in an unprotected area upon retraction of the needle into the cartridge.

Still another advantageous feature of this invention is that a retractable needle cartridge-needle unit is provided which can be used in conjunction with conventional commercially available prefilled medication cartridges and both disposable and reusable holders.

The invention will now be described with reference to, but in no way limited thereby, the following Figures in which

Figure 1 is a cross-sectional exploded view of a preferred embodiment of a cartridge-needle unit of this invention and an associated disposable holder.
Figure 2 is a cross-sectional view of the embodiment of Figure 1 in an assembled position.
Figures 3-7 are cross-sectional views of a cartridge needle in accordance with this invention illustrating the sequence of operation.
Figures 8 and 9 are perspective views of a washer-dart-needle combination in accordance with a preferred embodiment of this invention.
Figures 10-12 are side, distal and proximal views of another washer-dart-needle combination in accordance with this invention.
Figure 13 is a perspective view of an alternative embodiment of this invention which features a dart retained in the hub by fingers.
Figure 14 is an enlarged cross-section of the hub-needle illustrated in Figure 2.
Figure 15 is a cross-section of a preferred embodiment of this invention after retraction wherein the plunger comprises a stud and the hub post protrudes through the septum.

This invention is hereinafter described particularly in regard to preferred embodiments featuring a prefilled medication cartridge, which is activated by the health care worker, and a safety syringe assembly. In addition, this invention is useful in conjunction with a wide variety of syringe assemblies featuring both disposable and reusable holders including those designed for use with cartridge-needle units that are sold in an activated form, and with other devices adapted to dispense fluids.

In a preferred embodiment, the cartridge-needle unit of this invention is used in conjunction with an activatable prefilled cartridge, preferably containing a fluid medication or the like.

Illustrated in Figure 1, prefilled cartridge 10 can be of a conventional design and can include a hollow transparent body, typically fabricated of glass. The cartridge can include head portion 12 and cylindrical body 14 which are coextensively joined together at a relatively narrow neck.

The cartridge-needle unit comprises septum 18 at the distal end of the body. The septum prevents contamination and leakage of the fluid contents of the cartridge and forms an air-tight, sterile seal. The septum can be fabricated of compliant, resilient, rubbery materials which tend to reseal after being pierced. Preferred materials exhibit a Shore A durometer hardness of from about 50 to about 70. Septums fabricated of materials meeting these criteria are commercially available.

The cartridge-needle unit comprises means for retaining the septum 18. In a preferred embodiment, this can take the form of end cap 16 which covers the septum. The cap preferably is of a diameter approximately equal to that of the distal end of the glass cartridge. The cap holds the septum in place at the distal end of the cartridge. The cap can be fabricated of any suitable material, such as a metal such as aluminum. Alternatively, the septum can be adhered to the distal end of the cartridge using a suitable adhesive. In another embodiment, the septum can be retained within a slot or other retaining means disposed preferably at the mouth or neck portion of the cartridge.

The cartridge-needle unit comprises plunger 20 which is sized to be received in and slidable axially and reciprocally through the interior of the cartridge. The plunger can be moved axially and distally through the cartridge for expulsing contents of the cartridge via needle cannula 22. The screw-threaded post extending proximally from the plunger can be mated to screw-threadable plunger rod of an associated holder for controlling the movement of the plunger through the interior of the cartridge.

It is contemplated that the plunger rod can be attached to the plunger by various techniques. For example, the plunger rod can be attached directly to the plunger rod through a snap fit. Prefilled cartridges such as described above are currently in widespread commercial use. It is a particular advantage that this invention is useful in conjunction with cartridges in widespread commercial use.

In accordance with this invention, a cartridge-needle unit is provided with a needle hub/needle assembly as described below, and a needle sheath. Needle hub 24 comprises sleeve 26 which is designed to be snapped over the distal end of the cartridge, thus attaching the needle hub to the cartridge in a manner such that the cartridge can be forced forward in the hub after medication delivery. When an end cap 16 is present, the hub sleeve 26 can move over the sides of the cap. The hub, in conjunction with the needle sheath, forms a sterile seal for the enclosed septum and needle. The cartridge-needle unit comprises means for retaining the needle within the hub during an injection. The cartridge-needle unit further comprises means for releasing the needle from the hub after the injection. Such means comprises an element attached to the needle, and having a diameter greater than the needle, which is capable of passing through the septum.

In a preferred embodiment, the means for releasing the needle from the hub comprises a washer 28 and dart 30 attached to the needle. The dart in conjunction with hub post 32 or the like prevents movement of the needle forward with respect to the hub, virtually eliminating the possibility that the needle can be released into the patient. Additionally, the dart is capable of passing through the septum 18. The dart can be frangibly connected to the washer. The washer and dart preferably can be fabricated as a unitary piece by conventional injection molding techniques. The dart can be fabricated of a brightly colored plastic, which serves as an indicator that the needle has been safely withdrawn into the cartridge.

After the medication has been delivered and the syringe removed from the patient, continued pressure on the plunger rod forces the cartridge forward, separating the dart from the washer. When this occurs, the dart is forced through the septum by means of the hub post and the needle becomes embedded in the plunger. The plunger rod can then be withdrawn, pulling the needle and dart completely within the cartridge. The proximal end of the dart preferably comprises a conical taper to facilitate passage through the septum. It is contemplated that the dart geometry and shape can vary depending, e.g. on the type of material to be penetrated. For example, the dart can be provided with a lengthly tapered body, and/or with one or more knifelike fins to facilitate penetration through the septum.

The dart preferably comprises an annular circumferential shoulder on the distal end which communicates with the proximal portion of the hub post, virtually eliminating the possibility that the needle can move forward with respect to the hub. As noted, this is a particular advantage of this invention inasmuch as prior art designs are susceptible to release of the needle into the patient.

A conventional needle, preferably a double ended needle, can be permanently affixed to the dart using

conventional techniques, e.g. using conventional adhesives such as an epoxy.

The hub post 32, which preferably is of a diameter approximately the same as the dart 30, forces the dart through the septum 18 when continued pressure on the plunger rod after medication delivery thrusts the cartridge forward with respect to the hub.

Additionally, the hub post 32 helps orient the needle during assembly and use, and helps prevent the dart from exiting the syringe when it is forced at least partially through the septum as illustrated in Figure 15. The hub can further comprise sheath post 34 having a cylindrical cavity therein, the diameter of which is slightly greater than the diameter of the needle such that recessed fluide well 36 is formed. The fluid well functions to retain any residual body fluid or medication left on the needle after it is withdrawn from the patient. The inner walls of the well can be provided with a slightly rougher surface finish to make them more receptive to wetting. The wall helps keep residual fluid out of both contact and sight. As noted, the fluid well provides an important safety advantage over the prior art. The outside diameter of the sheath post 34 can be sized to accept the needle sheath and can comprise an annular circumferential seal ring to provide a sterile seal. The inside diameter of the hub 24 preferably contains an annular ring or bumps to retain the washer 28 and dart 30 in the hub before and/or during injection.

In an alternative embodiment, the means for retaining the needle 22 within the hub 24 during the injection can comprise inwardly extending fingers 38, as depicted in Figure 13, which hold the element, e.g. the dart 30, attached to the needle by engaging slots 40 in the side of the dart. In this embodiment, the element attached to the needle need not be frangibly connected to the hub. Nevertheless, in use, after medication has been delivered and the syringe removed from the patient, continued pressure on the plunger rod forces the cartridge forward, separating the dart from the fingers, forcing the dart through the septum, and imbedding the needle into the plunger.

The cartridge-needle unit can be provided with means for tilting, i.e. offsetting the needle, comprising a relatively resilient, non-compliant member which can be fabricated of a rigid material, such as, e.g. a metal or plastic. Compared to a compliant member, e.g. a rubber plunger, the non-compliant member can enhance the degree to which the needle is tilted or offset. In one embodiment, the plunger can be provided with an internal metal or rigid plastic plate. In another embodiment, the plunger rod can function as the means for tilting the needle, e.g. when the rod is attached directly to the plunger via a snap fit. In a preferred embodiment, the non-compliant member, upon contact with the needle, can cause the needle to deform, e.g., by bending the tip or body. Such deformation of the tip is advantageous inasmuch as it increases the force through which the needle is retained, e.g. in the plunger, thus facilitating reliable needle retraction. Additionally, the interference caused by the non-compliant member forces the needle to tilt or offset toward the cartridge wall. When the retracted needle is tilted toward the cartridge wall and the cartridge-needle unit is provided with a hub post 32 designed to protrude through the septum 18 after retraction as described below, the retracted needle is virtually precluded from exiting the cartridge through the port in the hub, even in the event that the plunger is pushed axially and distally forward.

In a preferred embodiment, the plunger can comprise stud 42, Figure 15, and the cartridge-needle unit and hub can be sized such that the needle tip contacts the plunger stud during the process of imbedding the needle in the plunger. This increases the propensity for the needle to tilt and increases the grabbing force by bending the fragile needle tip upon hitting the stud. The bent needle tip advantageously increases the force required to remove the needle from the plunger after it is imbedded therein. Moreover, the tilt makes it more difficult for the needle to be inadvertently forced out of the cartridge. In a preferred embodiment illustrated in Figure 15, the hub post 32 protrudes through the septum 18 after retraction. This feature, in combination with the studded plunger, makes it virtually impossible for the needle to leave the cartridge after it has been withdrawn therewithin. Additionally, when the septum closes upon the hub post, i.e. when the dart goes fully through the septum, the septum advantageously provides no further resistance as the dart and needle are withdrawn into the cartridge.

One distinct advantage of this invention is that it provides protection to the health care worker through removal of a sharp, used needle into the glass cartridge. This prevents the needle from puncturing gloves and/or skin and contaminating the health care worker with a potentially diseased body fluid of the patient. A less tangible but perhaps equally important aspect of the invention is the impression it makes upon the health care worker, i.e. by sealing the used needle safely within the glass, the user is convinced that the device is a safe one. As noted, by fabricating the dart of a brightly colored plastic, the dart functions as an indicator to the health care worker that the needle has been safely withdrawn within the cartridge. It is also contemplated that the needle can be brightly colored such that the needle functions as the indicator. For example, a portion of the needle can be provided with a coating of a brightly colored paint.

The hub, the means for retaining the needle in the hub and the means for releasing the needle from the hub can be fabricated of any suitable material including metals and plastic. However it is a particular advantage that the above-described designs are well adapted to be fabricated of plastic. In particular, it is preferred that the hub and means for retaining and releasing the needle be fabricated of rigid plastic using known precision injection molding techniques. Suitable plastics include,

polypropylene, polystyrene, polycarbonates, ABS (clear or opaque), nylon, acetals, polyethylene or polyester.

The cartridge-needle unit of this invention can be used in conjunction with any disposable or reusable holder, appropriately sized to accept the cartridge-needle unit. In a preferred embodiment, the holder is disposable, i.e. a single use holder. A preferred holder, depicted in Figures 1 and 2, comprises a hollow body sized for housing the cartridge-needle unit therein. In a preferred embodiment, the holder is provided with a tamper-evident "flip top" cap having a cam. The tamper-evident cap allows the medical worker to remove the seal without having to dispose of a separate part. The cap remains out of the way during the sequence of medication delivery and safety activation.

In a particularly preferred embodiment, the holder is provided with an "over-travel" cap. Such cap prevents the contaminated needle and plunger from exiting the cartridge and creating a potential safety hazard. The "over-travel" cap can be molded integrally with the body, such that the process of activating the cartridge also locks the cap in place.

In a particularly preferred embodiment, the holder can be provided with a connecting member between the cap and the body of the holder. For example, the connecting member can be a relatively straight tether or set of tethers between the cap and body. The connecting member can comprise means for predisposing the connecting member to fold in a specified, e.g. outward, direction. For example, pairs of foldable tethers 46 (Figures 1 and 15) permit the retaining "over-travel" cap and/or tamper-evident "flip top cap" to be permanently attached to the body. The holder can be further provided with pairs of biasing triangles 44 which bias the tethers outwardly from the body when the cartridge is inserted into the holder during assembly. When the cartridge is activated, the tethers fold and position the "over-travel" cap to prevent the plunger and needle from being pulled out of the cartridge during retraction.

In use, with reference to Figures 3-7, an activatable cartridge-needle unit in accordance with this invention operates in conjunction with a disposable holder during and after administration of an injection site as follows. The syringe assembly is received by the health care worker and the plunger rod is detached from the body of the holder. The cartridge-needle unit is activated, i.e. the proximal end of the needle is caused to pierce the septum and the cartridge is moved forward in the hub, preferably by application of an axial and distal force to a tamper-evident cap. The flip top is then rotated out of the way to expose the post, e.g. a screw threaded post, of the plunger. The plunger rod is screwed onto the post. The needle is then inserted into the injection site, and the medication is delivered to the patient by the health care worker applying an axially and distally directed force to the plunger rod through the thumb pad. Thereafter, the syringe is removed from the injection site. Continued application of an axially and distally directed force on the plunger rod causes the cartridge to slide forward in the hub, breaking the washer-dart. This forces the dart through the septum and embeds the needle into the plunger. The plunger rod is then retracted, permanently capturing the needle, dart and plunger completely within the cartridge. The plunger and needle can be prevented from being pulled out of the cartridge by the auxiliary "over-travel" cap which can be snapped in place as the cartridge is activated. It is contemplated that an automatic needle withdrawal system can be implemented with this invention.

Claims

1. A cartridge-needle unit comprising:

   a cartridge (10) comprising:

   a hollow body (14),
   a septum (18) at the distal end of said body (14),
   means (16) for retaining the septum (18), and
   a plunger (20), axially and reciprocally slidable through the interior of said body (14);

   a needle (22) capable of being retracted within said cartridge (10);
   a hub (24) comprising:

   a sleeve (26) adapted to be snapped on the distal end of said cartridge (10),
   means (28,30,32,38) for retaining said needle (22) within the hub (24) during an injection; and
   means (28,30,32) for releasing the needle (22) from the hub (24) after the injection characterized in that said means (28,30,32) for releasing the needle (22) from the hub (24) and said means for retaining the needle (22) within the hub (24) comprise an element (30) of greater diameter than said needle and attached thereto, said element abutting against a hub post (32) before and during injection and being capable of passing through the septum, said hub post being capable of forcing the element through the septum after injection and said element (30) being adapted to separate from the remaining needle retaining means, with a continued application of an axially and distally directed force on the plunger (20), the needle thus embedding into the plunger.

2. A cartridge-needle unit as claimed in claim 1 wherein said means for releasing the needle (22) from the hub (24) comprises a washer (28) and a

dart (30) attached to said needle (22), wherein said dart (30) is capable of passing through said septum (18).

3. A cartridge-needle unit as claimed in claim 2 wherein said dart (30) is frangibly connected to said washer (28).

4. A cartridge-needle unit as claimed in any one of claims 1 to 3 wherein said hub (24) comprises a fluid well (36).

5. A cartridge-needle unit as claimed in any one of claims 1 to 4 wherein said means for retaining the septum (18) comprises an aluminum cap (16).

6. A cartridge-needle unit as claimed in any one of claims 1 to 5 wherein said plunger (20) comprises a stud (42).

7. A cartridge-needle unit as claimed in either of claims 2 and 3 wherein said hub (24) comprises a post (32) capable of forcing said dart (30) through said septum (18).

8. A cartridge-needle unit as claimed in either of claims 2 and 3 wherein said dart (30) is fabricated of a brightly colored plastic.

9. A cartridge-needle unit as claimed in any one of claims 1 to 8 further comprising means for tilting the needle (22) comprising a non-compliant member.

10. A syringe assembly comprising the cartridge-needle unit of claim 1 and a holder therefor.

11. An assembly as claimed in claim 10 wherein said holder is a disposable holder.

12. An assembly as claimed in either of claims 10 and 11 wherein said holder comprises a cap sized to prevent the plunger (20) and needle (22) from being pulled out of the cartridge (10).

13. An assembly as claimed in claim 12, wherein said holder comprises a holder body and a connecting member between said cap and said holder body.

14. An assembly as claimed in claim 13 wherein said connecting member comprises a foldable tether (46).

15. An assembly as claimed in either of claims 13 to 14 wherein said connecting member comprises means for predisposing the connecting member to fold in an outward direction from the holder body.

16. An assembly as claimed in claim 15 wherein said means for predisposing the connecting member to fold comprises a biasing triangle (44).

Patentansprüche

1. Einheit aus Kartusche und Nadel mit:

   einer Kartusche (10) mit:

   - einem hohlen Körper (14)
   - einer Trennwand (18) am entfernten Ende des Körpers (14);
   - Mitteln (16) zum Halten der Trennwand (18); und
   - einem Kolben (20), der im Inneren des Körpers (14) axial hin und her verschiebbar ist;
   - einer Nadel (22), die in die Kartusche (10) zurückgezogen werden kann;
   - einer Nabe (24) mit:

     - einer Hülse (26), die auf das entfernte Ende der Kartusche (10) aufgerastet werden kann;
     - Mitteln (28,30,32,38) zum Halten der Nadel (22) innerhalb der Nabe (24) während der Injektion; und
     - Mitteln (28,30,32) zum Lösen der Nadel (22) von der Nabe (24) nach der Injektion

   dadurch **gekennzeichnet**, daß diese Mittel (28,30,32) zum Lösen der Nadel (22) von der Nabe (24) und die Mittel zum Halten der Nadel (22) innerhalb der Nabe (24) ein Element (30) umfassen, das einen größeren Durchmesser als die Nadel aufweist, welches Element vor und während der Injektion gegen einen Nabenvorsprung (32) anliegt und durch die Trennwand hindurchgehen kann, welcher Nabenvorsprung in der Lage ist, das Element nach der Injektion durch die Trennwand hindurchzudrücken, welches Element (30) von den übrigen Nadel-Haltemitteln trennbar ist bei fortgesetzter Anwendung einer axial und nach hinten gerichteten Kraft des Kolbens (20), so daß die Nadel in den Kolben eingebettet wird.

2. Kartuschen-Nadel-Einheit nach Anspruch 1, bei der die Mittel zum Lösen der Nadel (22) von der Nabe (24) eine Scheibe (28) und eine Spitze (30) umfassen, die an der Nadel (22) angebracht ist, wobei die Spitze (30) in der Lage ist, durch die Trennwand (18) hindurchzugehen.

3. Kartuschen-Nadel-Einheit nach Anspruch 2, bei der die Spitze (30) abbrechbar mit der Scheibe (28) verbunden ist.

4. Kartuschen-Nadel-Einheit nach einem der Ansprüche 1 bis 3, bei der die Nabe (24) einen Fluidkanal (36) aufweist.

5. Kartuschen-Nadel-Einheit nach einem der Ansprüche 1 bis 4, bei der die Mittel zum Halten der Trennwand (18) eine Aluminiumkappe (16) umfassen.

6. Kartuschen-Nadel-Einheit nach einem der Ansprüche 1 bis 5, bei der der Kolben (20) einen Ansatz (42) aufweist.

7. Kartuschen-Nadel-Einheit nach einem der Ansprüche 2 und 3, bei der die Nabe (24) einen Nabenvorsprung (32) aufweist, der in der Lage ist, die Spitze (30) durch die Trennwand (18) zu drücken,

8. Kartuschen-Nadel-Einheit nach einem der Ansprüche 2 und 3, bei der die Spitze (30) aus einem hell eingefärbten Kunststoff besteht.

9. Kartuschen-Nadel-Einheit nach einem der Ansprüche 1 bis 8, mit Mittein zum Kippen der Nadel (22), die ein nicht-nachgiebiges Teil umfassen,

10. Spritzenanordnung mit der Kartuschen-Nadeleinheit des Anspruchs 1 und einem Halter für diese.

11. Anordnung nach Anspruch 10, bei der der Halter ein wegwerfbarer Halter ist.

12. Anordnung nach einem der Ansprüche 10 und 11, bei der der Halter eine Kappe ist, die so bemessen ist, daß sie ein Herausziehen des Kolbens (20) und der Nadel (22) aus der Kartusche (10) verhindert.

13. Anordnung nach Anspruch 12, bei der der Halter einen Halterkörper und ein Verbindungsglied zwischen der Kappe und dem Halterkörper umfaßt.

14. Anordnung nach Anspruch 13, bei der das Verbindungsglied ein faltbares Seil (46) ist.

15. Anordnung nach einem der Ansprüche 13 bis 14, bei der das Verbindungsglied Mittel zur Vorentsorgung des Verbindungsgliedes zur Faltung in Auswärtsrichtung in bezug auf den Halterkörper aufweist.

16. Anordnung nach Anspruch 15, bei der die Mittel zur Vorentsorgung des Verbindungsgliedes durch Faltung ein vorgespanntes Dreieck (44) umfaßt.

Revendications

1. Ensemble de cartouche et aiguille comprenant :

   - une cartouche (10) comprenant :
     - un corps creux (14),
     - une cloison (18) à l'extrémité distale dudit corps (14),
     - des moyens (16) pour retenir la cloison (18), et
     - un plongeur (20), coulissant axialement et suivant un mouvement de va-et-vient à l'intérieur dudit corps (14),
     - une aiguille (22) capable d'être rétractée dans ladite cartouche (10),
     - un moyeu (24) comprenant :
       - une douille (26) conçue pour être enclenchée sur l'extrémité distale de ladite cartouche (10),
       - des moyens (28, 30, 32, 38) pour retenir ladite aiguille (22) à l'intérieur du moyeu (24) pendant une injection, et
       - des moyens (28, 30, 32) pour libérer du moyeu (24) l'aiguille (22) après l'injection,

   caractérisé en ce que lesdits moyens (28, 30, 32) pour libérer du moyeu (24) l'aiguille 22 et lesdits moyens pour retenir l'aiguille (22) à l'intérieur du moyeu (24) comprennent un élément (30) de plus grand diamètre que ladite aiguille et fixé à celle-ci, ledit élément venant buter contre un montant (32) du moyeu avant et pendant une injection et étant capable de traverser la paroi, ledit montant de moyeu étant capable de pousser l'élément à travers la paroi après injection et ledit élément (30) étant conçu pour se séparer du reste des moyens de retenue de l'aiguille, avec une application continue d'une force dirigée dans les sens axial et distal sur le plongeur (20), l'aiguille étant ainsi incorporée dans le plongeur.

2. Ensemble de cartouche et aiguille selon la revendication 1, dans lequel lesdits moyens pour libérer du moyeu (24) l'aiguille (22) comprennent une rondelle (28) et un dard (30) fixé à ladite aiguille (22), dans lequel ledit dard (30) est capable de traverser ladite cloison (18).

3. Ensemble de cartouche et aiguille selon la revendication 2, dans lequel ledit dard (30) est relié de manière fragile avec ladite rondelle (28).

4. Ensemble de cartouche et aiguille selon l'une quelconque des revendications 1 à 3, dans lequel ledit moyeu (24) comporte un réservoir (36) à fluide.

5. Ensemble de cartouche et aiguille selon l'une quelconque des revendications 1 à 4, dans lequel lesdits moyens pour retenir la cloison (18) comprennent un capuchon (16) en aluminium.

6. Ensemble de cartouche et aiguille selon l'une quel-

conque des revendications 1 à 5, dans lequel ledit plongeur (20) comporte un goujon (42).

7. Ensemble de cartouche et aiguille selon l'une ou l'autre des revendications 2 et 3, dans lequel ledit moyeu (24) comporte un montant (32) capable de pousser ledit dard (30) à travers ladite cloison (18).

8. Ensemble de cartouche et aiguille selon l'une ou l'autre des revendications 2 et 3, dans lequel ledit dard (30) est fabriqué en matière plastique de couleur vive.

9. Ensemble de cartouche et aiguille selon l'une quelconque des revendications 1 à 8, comprenant en outre des moyens pour faire basculer l'aiguille (22) qui comportent un organe non souple.

10. Ensemble de seringue comprenant l'ensemble de cartouche et aiguille de la revendication 1 et un support pour celui-ci.

11. Ensemble selon la revendication 10, dans lequel ledit support est un support jetable.

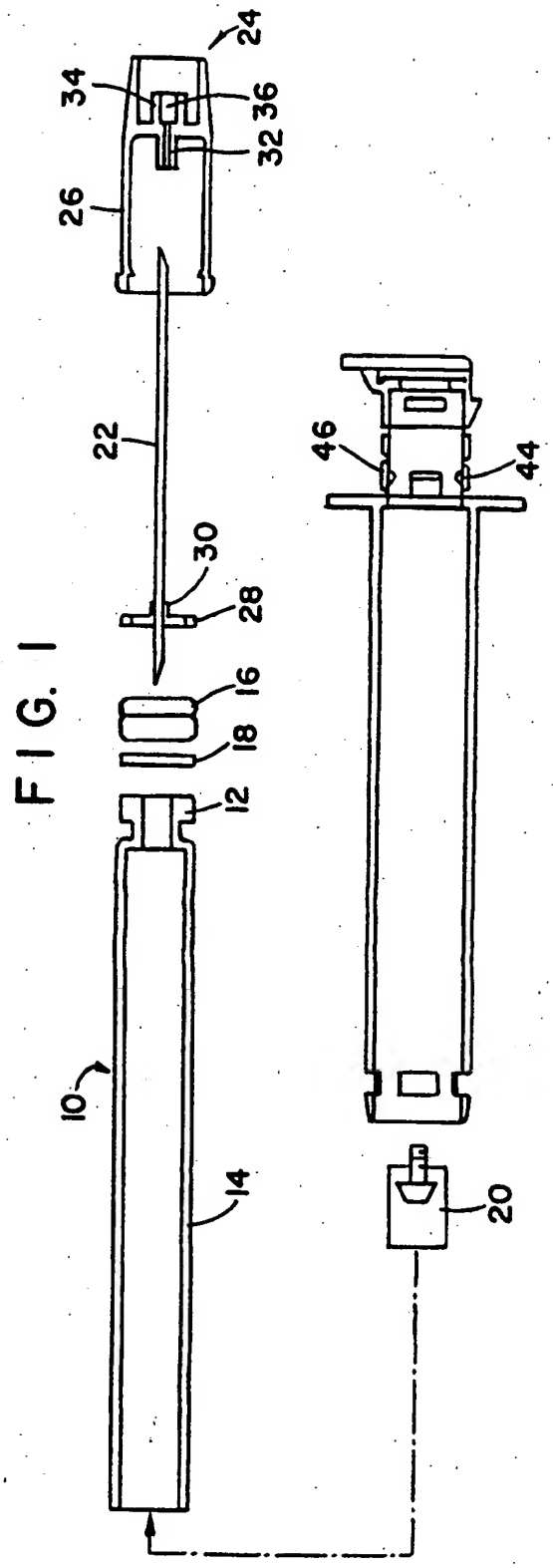
12. Ensemble selon l'une ou l'autre des revendications 10 et 11, dans lequel ledit support comporte un capuchon d'une taille lui permettant d'empêcher le plongeur (20) et l'aiguille (22) d'être retirés de la cartouche (10).

13. Ensemble selon la revendication 12, dans lequel ledit support comporte un corps formant support et un organe de raccordement entre ledit capuchon et ledit corps formant support.

14. Ensemble selon la revendication 13, dans lequel ledit organe de raccordement comporte une attache pliable (46).

15. Ensemble selon l'une ou l'autre des revendications 13 à 14, dans lequel ledit organe de raccordement comporte des moyens pour prédisposer l'organe de raccordement à se plier dans une direction extérieure depuis le corps formant support.

16. Ensemble selon la revendication 15, dans lequel lesdits moyens pour prédisposer l'organe de raccordement à se plier comprennent un triangle de sollicitation (44).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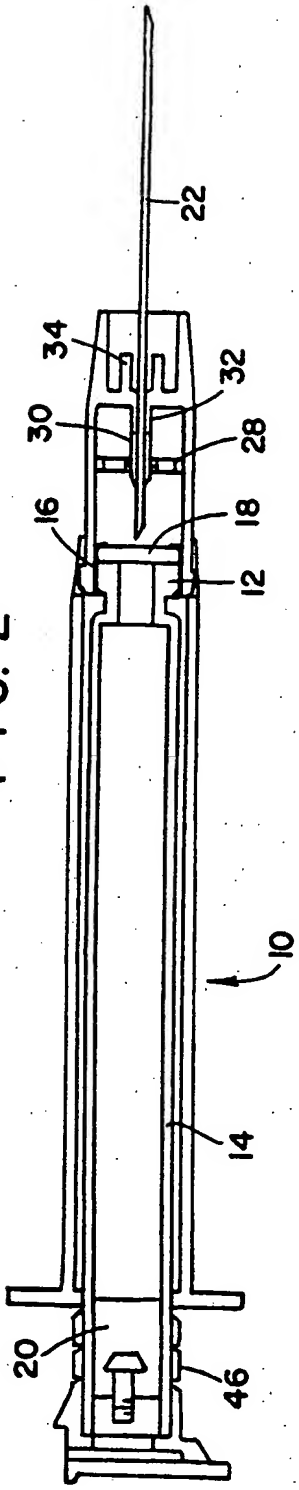
44
20

FIG. 1


22
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28
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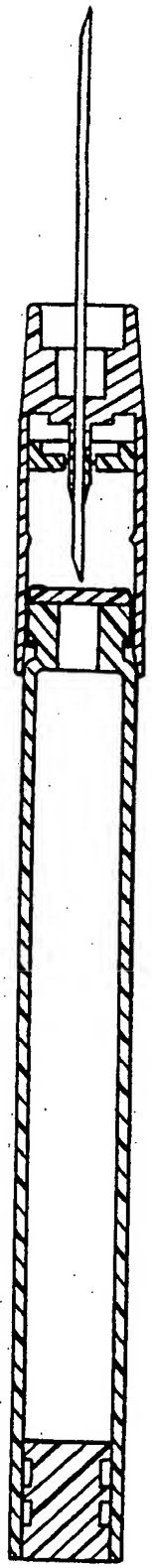
46

FIG. 2

FIG. 3



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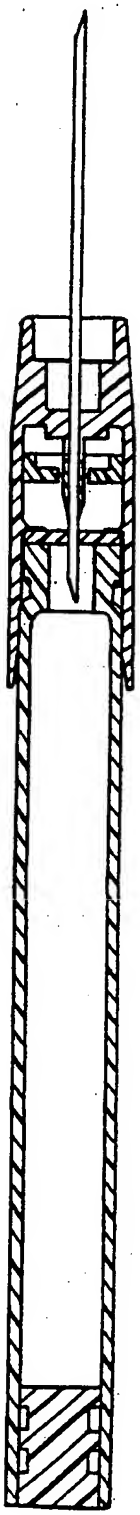


FIG. 5

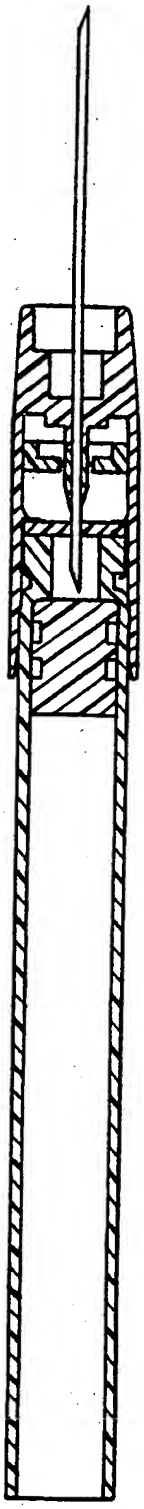


FIG. 6

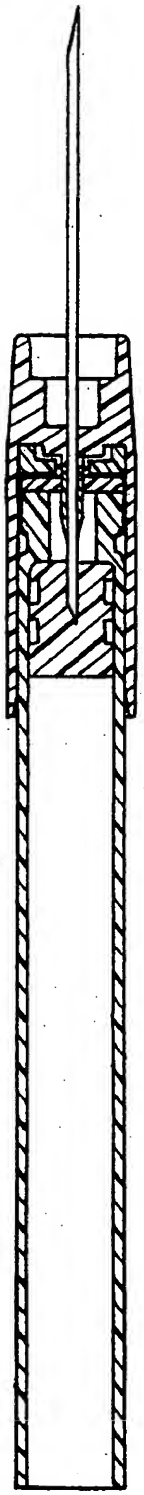
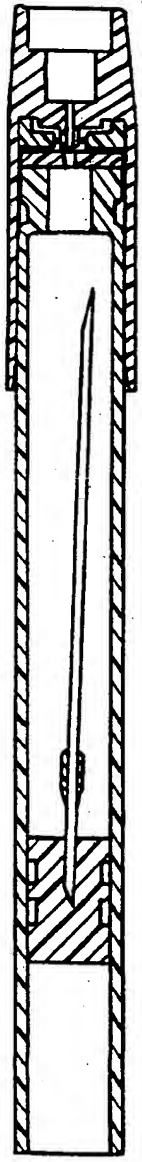
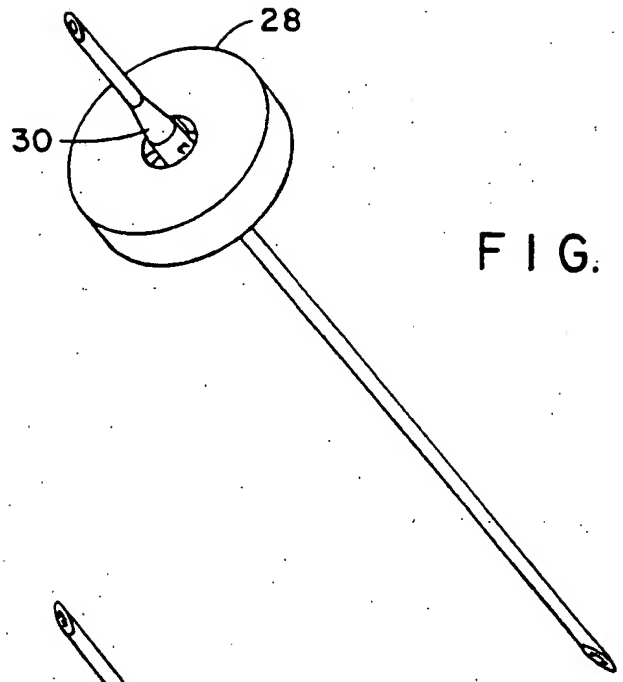


FIG. 7





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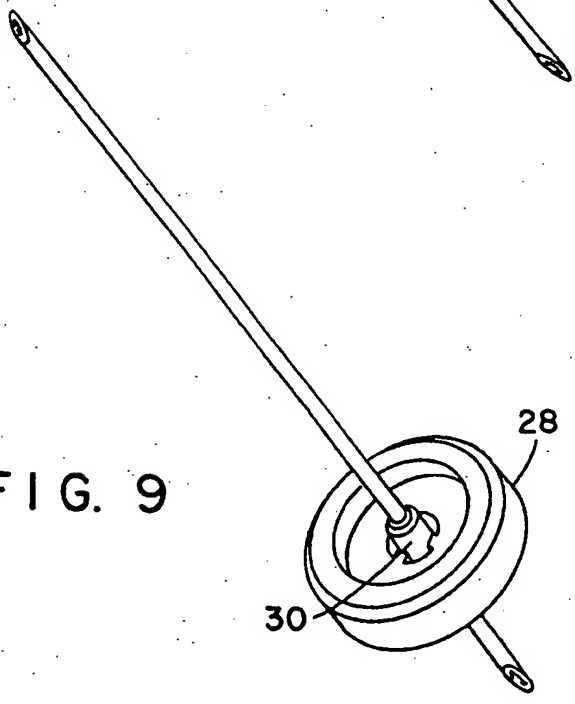

FIG. 9

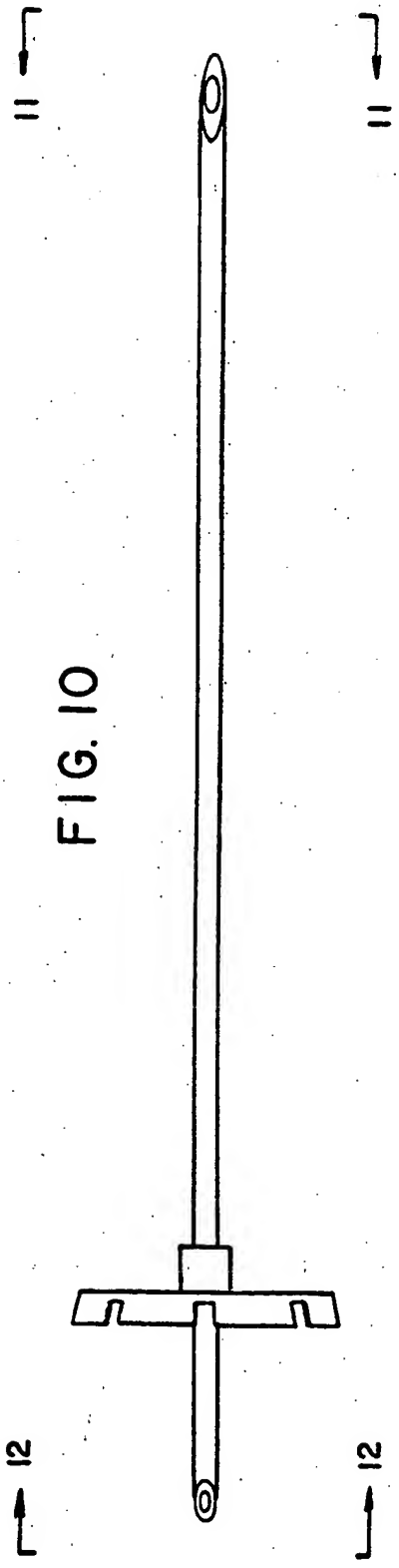

FIG. 10

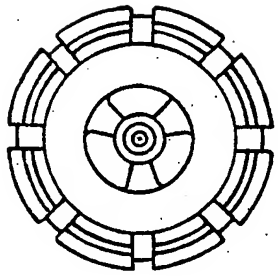

FIG. 12

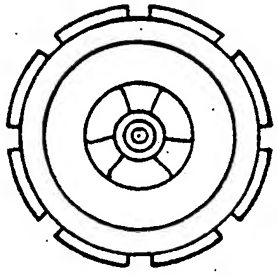

FIG. 11

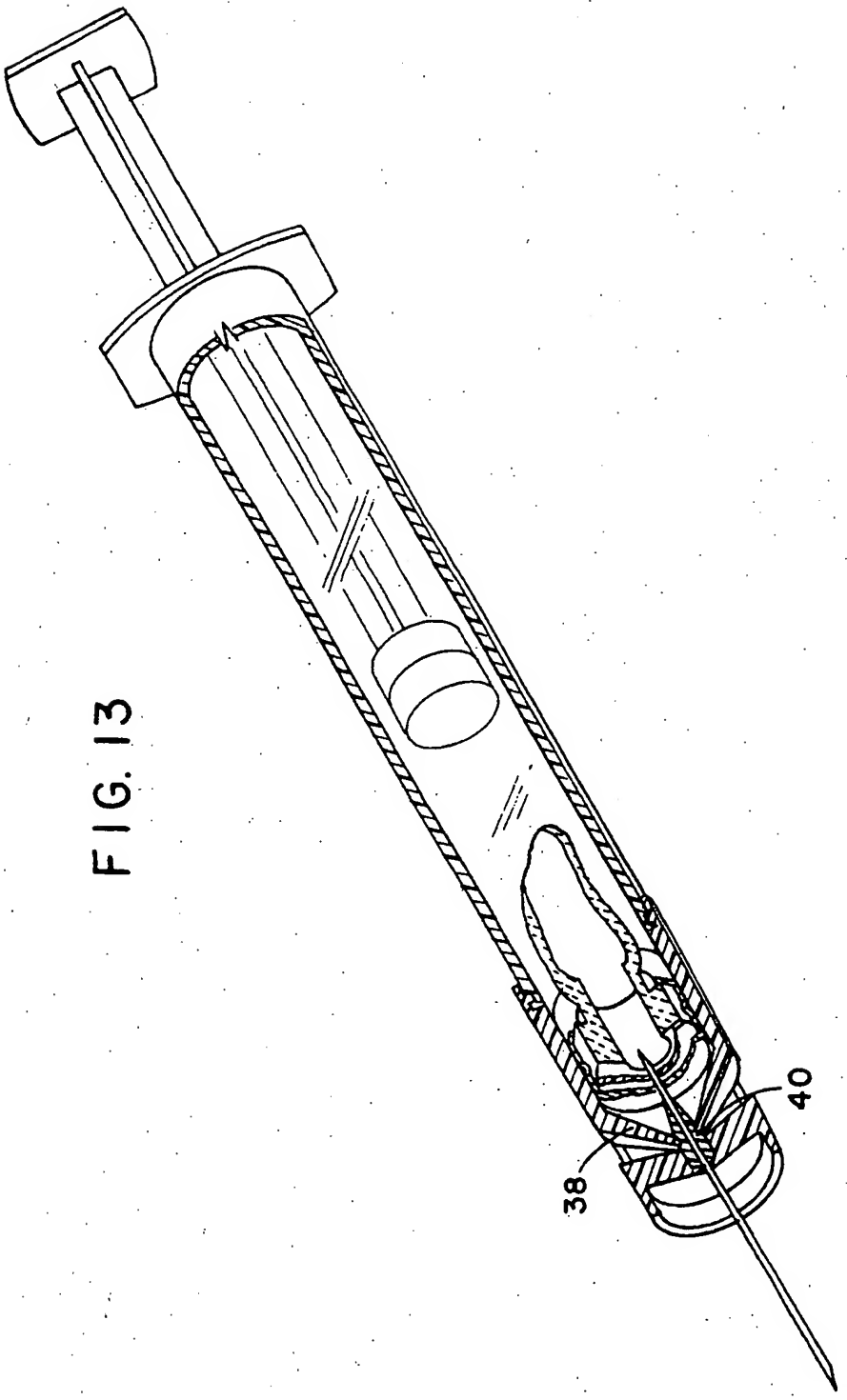

FIG. 13

FIG. 14

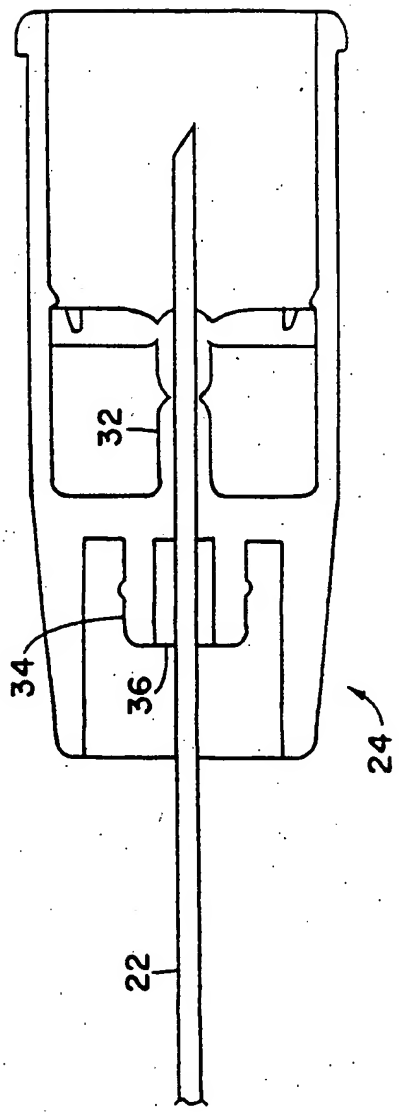

FIG. 15